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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,035	08/15/2006	Jan Skansen	1505-1041-1	6755

466 7590 08/10/2009

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EXAMINER	
PATEL, SHEFALI DILIP	
ART UNIT	PAPER NUMBER
3767	
MAIL DATE	DELIVERY MODE
08/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,035	SKANSEN ET AL.	
	Examiner	Art Unit	
	SHEFALI D. PATEL	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 May 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-22,24-29,31,33 and 38-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22,24-29,31,33 and 38-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgments

1. In the reply, filed on May 21, 2009, Applicant amended claims 19, 24, 25.

2. Applicant cancelled claim 34.

3. Applicant added new claims 38-40.

4. In the non-final rejection of February 26, 2009, Examiner objected to claims 24 and 25 for minor informalities. Applicant amended said claims. Objections are withdrawn.

5. Examiner rejected claims 19 under 35 USC 112, 2nd paragraph, as the specification does not contain a recitation of the structure associated with the "control means". Applicant amended the "control means" recitations to be "controller" recitations. Rejection is withdrawn.

6. Currently, claims 19-22, 24-29, 31, 33, and 38-40 are under examination.

Response to Arguments

7. Applicant's arguments with respect to claims 19-22, 24-29, 31, 33, and 34 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter ("a volume of the flushing liquid is equal to or slightly larger than the volume defined in said outer catheter lumen") not previously presented in the claims into independent claim 19.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 19-22, 25, and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter (US 2003/0216685), and further in view of Lang (US 5,609,572).

In regards to claims 19 and 38-40, Porter teaches an infusion system comprising a catheter device (Figures 1 and 1A-1D, catheter device [10]) comprising:

a. an outer catheter (outer tubular element [20]) provided with one outer catheter lumen (lumen [28]) with a distal outer catheter outflow opening (opening at distal tip [25]), and an inner catheter (inner tubular element [22]) provided with at least one inner catheter lumen (lumen [34]) with at least one distal inner catheter outflow opening (opening at distal tip [31]), said inner catheter is adapted to be detachably arranged in said outer catheter lumen (Figure 1B), said inner catheter outflow opening is located proximally said outer catheter outflow opening when the catheter device is adapted to be used for administration of liquid substances to a patient (Figure 1)

b. wherein the infusion system further comprises an external pump device including a pumping means and a reservoir means (first supply [34] and second supply [36] which contain first fluid component [12] and second fluid component [14], respectively; either of supplies [34][36] may be a pump) (paragraph [0038])

c. wherein a liquid pulse of a liquid substance (second fluid component [14]) through the inner catheter lumen [34] is followed in time sequence by a liquid pulse of a flushing liquid (first fluid component [12]) applied through the outer catheter lumen [28], in order to make the liquid substance reach a target area of administration (paragraph [0061])

d. the volume of the liquid pulse of the substance [14] is approximately the same as the volume (mixing zone [38]) defined in said outer catheter lumen [28] between the inner catheter outflow opening and the outer catheter outflow opening (paragraph [0061])

Porter is silent about whether the external pump device [34][36] comprises a controller, wherein said controller controls the pumping means such that said substance is administered as a pulsed flow sequence of liquid substance comprising a predetermined number of liquid pulses. Porter is also silent about whether a volume of the flushing liquid [12] is equal to or slightly larger than the volume defined in said outer catheter lumen [28]. Lang teaches an infusion system (Figure 9), wherein an external pump device comprises a pumping means (pump cassette [A2] + pump actuating device [B2] + infusion distribution cassette [D]), a reservoir means (infusion containers [71][72][73][74][75]), and a controller (control device [C79]). Lang further teaches that the controller [C79] controls the pumping means [A2][B2][D] such that a substance is administered as a pulsed flow sequence (Abstract)(column 2, lines 30-37). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the external pump device, of the infusion system of Porter, with a controller that directs a substance to pulsatile flow, as taught by Lang, as a suitable programming controller makes it possible for vascular access points to be maintained open by pulsating fluid infusion (column 2, lines 30-32).

Further, concerning the limitation that the volume of the flushing liquid is equal to or slightly larger than the volume defined in said outer catheter lumen, such would depend upon the volume of flushing liquid necessary and prescribed by the user for moving the active substance from the catheter to the patient's body. Alone, Porter teaches that one volume introduction of the flushing liquid [12] is less than the volume defined in the outer catheter lumen [28], as the flushing liquid only reaches the mixing zone [38] at first, and Porter is silent about the total volume of flushing liquid contained in the first supply [34] (paragraph [0061]). However, with a second volume introduction of flushing liquid, as taught by the combination of Porter and Lang, one would expect the total volume of the first volume introduction and the second volume introduction of flushing liquid to together be larger than the volume of the outer catheter lumen of Porter. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the volume of the flushing liquid to be slightly larger than the volume defined in the outer catheter lumen, in an infusion system of Porter and Lang, as such a volume will accommodate for more than one introduction of flushing liquid into the patient for delivery of more than one volume of active substance. *In Applicant's specification, the pumping means is at least two pumps, and the reservoir means is one or more reservoirs.*

In regards to claim 20, in a modified system of Porter and Lang, Porter teaches that said inner catheter [22] is coaxially arranged with regard to said outer catheter [20] (Figure 1).

In regards to claim 21, in a modified system of Porter and Lang, Porter teaches that at least one substance [14], adapted to be administered, is active, and is a pharmaceutical preparation for therapeutic or diagnostic use (Abstract)(paragraphs [0012][0061]).

In regards to claim 22, in a modified system of Porter and Lang, Porter teaches that said substance [14] is administered by said inner catheter [22] (paragraph [0039]).

In regards to claim 25, in a modified system of Porter and Lang, Porter teaches that said catheter device [10] is provided with a second connector means (connector [23]) making it possible to detach said inner catheter [22] and replace it (Figure 1B).

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porter and Lang, as applied to claim 19 above, and further in view of Griego et al (US 6,663,596).

In regards to claim 24, in a modified system of Porter and Lang, Porter teaches that the outer and inner catheters [20][22] comprises at their respective proximal ends [26][32] first connector means (connector [23]) for connection to an external pump device having one or more reservoirs [34][36] for substances and flushing liquids (paragraph [0038]). However, in Applicant's specification, the first connector means is a pair of connector parts (page 10, lines 6-9). Porter only teaches that the first connector means is one connector [23]. Griego et al teaches a catheter device (Figure 10a-10b, delivery system [16]) with outer and inner catheters (first elongated member [100] and second elongated member [200]) having first connection means (connection ports or seals [170][270]) at their respective proximal ends for connection to an external pump device (first pump [183] and second pump [283]) having reservoirs (reservoirs [196][296]) for substances and flushing liquids (first and second materials, *not referenced*). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to substitute the one connector, of the catheter device of the modified infusion system of Porter and Lang, with two connectors of a first connection means, as taught by Griego et al, as

providing each one of the inner and outer catheters with their own separate connector to a respective reservoir of the external pump device will allow each one of the catheters to be connected and disconnected from the external pump device without connecting or disconnecting the other one of the catheters from the external pump device (i.e. with respect to the one connector of Porter, both catheters must be connected or disconnected from the external pump device at the same time since there is only one connector) (Griego et al, column 8, lines 21-27). *In Applicant's specification, the first connector means is a pair of connector parts (page 10, lines 6-9).*

11. Claims 26-29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porter and Lang, as applied to claims 19 and 25 above, and further in view of Balbierz et al (US 5,156,596).

In regards to claim 26, in a modified system of Porter and Lang, Porter does not teach that said second connector means [23] is partly integrated in a Y-connection. Balbierz et al teaches a catheter device (Figures 3-5, catheter assembly [10]) with a second connector means (inner lumen positioning assembly [38] with Luer locking mechanism [66]) for detachably arranging an inner catheter [52] within an outer catheter [28], wherein the second means [38] comprises a Y-connection ("Y-shape") (column 7, lines 22-53). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the second connector means, of the modified system of Porter and Lang, with a second connector means having a Y-connection, as taught by Balbierz et al, as the second connector means having a Y-connection as the two proximal access regions of the Y-connection will allow non-compatible

medicaments to be introduced into the body at a spaced distance apart from one another (column 7, lines 22-53).

In regards to claims 27-29, in a modified system of Porter, Lang, and Balbierz et al, Porter teaches that the second connector means [23] includes a first fastening means (indentation [60]) at the proximal end of said inner catheter [22] adapted to co-operate with a second fastening means (ridge [62]) integrated with an opening in the outer catheter wall [20] such that when said first and second fastening means are attached to each other the catheter is in a substance administration state (Figure 1).

In regards to claim 31, in a modified system of Porter and Lang, Porter does not teach that the inner catheter [22] comprises two lumen, as Porter only teaches one inner catheter lumen [34]. Balbierz et al teaches a catheter device (Figure 11) comprising an inner catheter (inner cannula [52]) with two lumen (passages [90][92]). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the inner catheter, of the modified system of Porter and Lang, with two lumen, as taught by Balbierz et al, as two lumen will allow the inner catheter to deliver two different substances to the patient, for example, if so desired by the user.

12. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Porter and Lang, as applied to claim 19 above, and further in view of Uldall (US 4,493,696).

In regards to claim 33, in a modified system of Porter and Lang, Porter does not teach that all surfaces in contact with the active substance [14] in the catheter device [10] are made of or covered by tetrafluoro polyethylene. Uldall teaches a catheter device (Figures 1-5, cannula

[10]), wherein all surfaces in contact with an active substance in the catheter device [10] are made of tetrafluoro polyethylene (column 3, lines 16-24). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the catheter device, of the modified system of Porter and Lang, to be made of tetrafluoro polyethylene, as tetrafluoro polyethylene has known biocompatibility for residence in a patient's body over extended periods of time (column 3, lines 16-24).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-

3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/
Examiner, Art Unit 3767
08/07/2009
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